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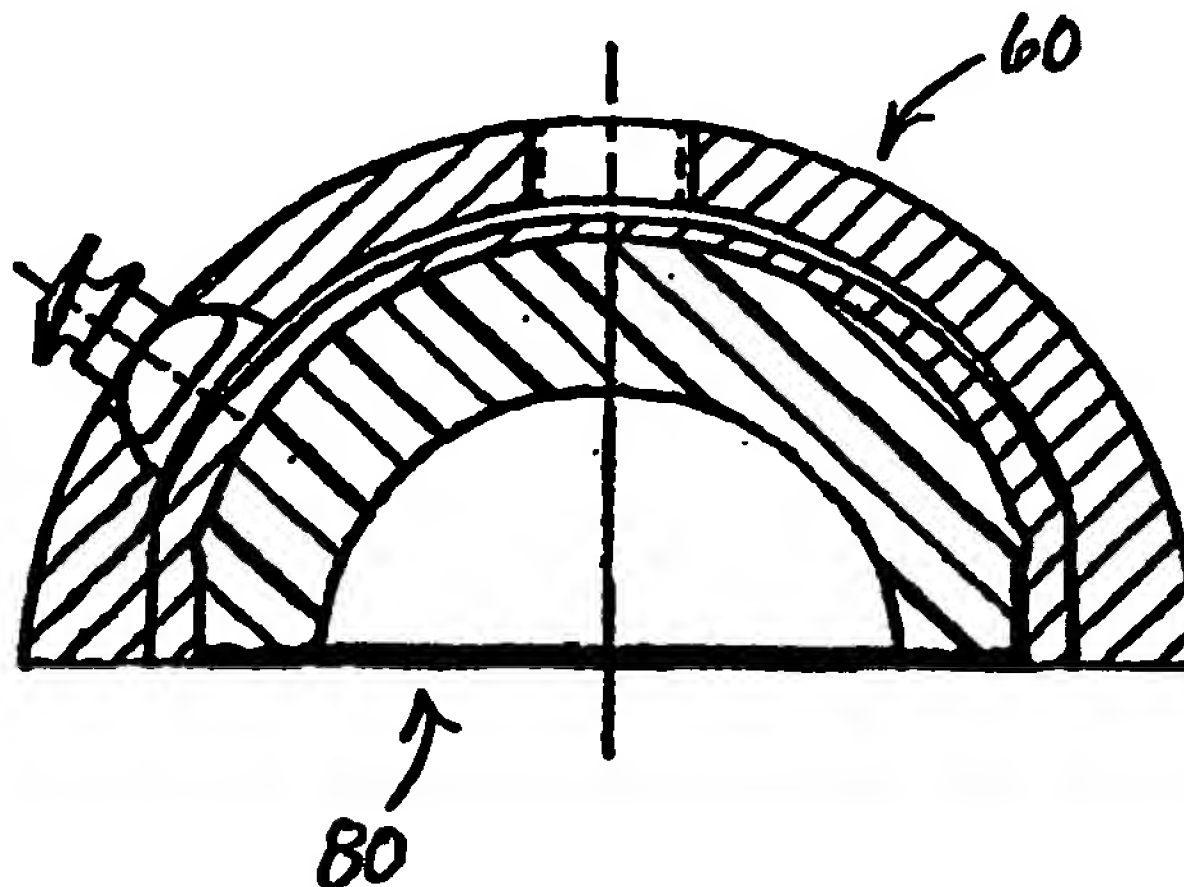
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(21) International Application Number: PCT/US95/02334 (22) International Filing Date: 24 February 1995 (24.02.95) (30) Priority Data: 08/201,688 25 February 1994 (25.02.94) US (71) Applicant: INTERMEDICS ORTHOPEDICS, INC. [US/US]; 1300 E. Anderson Lane, Austin, TX 78752 (US). (72) Inventor: BIRK, Janel, A.; 22935 Erwin Street, Woodland Hills, CA 91367 (US). (74) Agent: ROBINSON, Richard, L.; Sulzermedica USA, Inc., 4000 Technology Drive, Angleton, TX 77515 (US).		(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published With international search report.

(54) Title: ACETABULAR CUP COMPOSITE INSERT AND ASSEMBLY METHOD

(57) Abstract

An acetabular prosthesis includes a hemispherical metal shell (60) for fixation to bone and a composite bearing (80) insert for receipt within the shell (60). The composite bearing insert (80) includes an inner plastic portion (80) having a plastic bearing surface defining a bearing concavity for receipt of and articulation with a head of an implantable femoral component. The composite bearing insert (80) further includes an outer metal portion (60) fixed thereto against relative movement and having a metal male conical taper surface. The interior of the metal shell has a female conical taper surface for engaging the male conical taper surface in a taper locked relationship to secure the composite bearing insert (80) within the shell (60). The inner plastic portion (80) and the outer metal portion (60) have a mutually engaging protrusion and groove that are assembled by cooling and shrinking the plastic portion relative to the metal portion during assembly. The interface between the shell (60) and the composite bearing (80) is entirely metal, thereby preventing plastic to metal micromotion and generation of polyethylene debris.



ACETABULAR CUP COMPOSITE INSERT AND ASSEMBLY METHOD

Technical Field

The present invention relates generally to implantable prostheses for human joint replacement, and relates more particularly to an acetabular cup for a total hip prosthesis.

5

Background Information

One known arrangement for a total hip prosthesis includes a femoral component and an acetabular cup component. The femoral component has a stem for receipt and fixation within the medullary canal at a resected proximal end of the femur, and has a spherical head that may be integral
10 with or removably attached to the stem. The acetabular cup component has an outer bone engaging surface for receipt within the acetabulum, and has a concave inner bearing surface for receiving the head of the femoral component. The head articulates in sliding relationship with the inner bearing surface such that the total hip prosthesis restores a normal range
15 of motion to an otherwise diseased or damaged hip joint.

It is known to provide an acetabular cup having an outer acetabular shell made of a biocompatible metal such as titanium or titanium alloy, and a bearing insert made of a biocompatible plastic such as ultra-high molecular weight polyethylene. The metal shell facilitates fixation of the
20 acetabular cup to bone, via bone screws received through holes in the shell, for example. The plastic bearing insert provides a low friction plastic bearing surface for articulation with the head of the femoral component, where the head is made of a hard, smoothly polished material such as cobalt chrome or ceramic. The acetabular shell is often shaped generally
25 as a hemispherical cup, defined by a generally hemispherical outer surface and a generally hemispherical inner surface. The inner wall defines a concavity for receipt of the bearing insert. The polyethylene bearing insert often has a generally hemispherical outer surface dimensioned to be received and fixed within the concavity of the acetabular shell, and has a

bearing cavity defined by a polyethylene inner bearing surface for articulation against the spherical head.

Although the bearing insert is usually designed to be received in non-articulating relationship relative to the acetabular shell, it is believed by
5 some researchers that a small amount of relative motion between the bearing insert and the acetabular shell can occur under the varying load that the acetabular cup is subjected to during use. Such small relative motion, or micro-motion, may result in wear at the interface between the bearing insert and acetabular shell, causing the generation of polyethylene
10 or metal debris. It has been suggested that such debris can migrate out of the acetabular cup and come in contact with bone, possibly resulting in osteolysis, which ultimately can lead to bone resorption and possible loosening of the acetabular prosthesis.

It would be desirable to provide an acetabular cup having a metal
15 shell and a bearing insert with a plastic bearing surface that is arranged to prevent micro-motion between the metal and plastic components. This and other desirable features are provided by the present invention.

Disclosure of the Invention

The present invention involves a composite bearing insert for
20 insertion within a shell to form an acetabular prosthesis for articulating engagement with a head of an implantable femoral prosthesis. In accordance with one embodiment of the invention, an acetabular prosthesis includes a shell for fixation to bone, with the shell having an inner surface defining a concavity. The inner surface includes a metal
25 female conical taper surface. Also included is a composite bearing insert for receipt within the concavity of the shell. The composite bearing insert includes an inner plastic portion having a plastic bearing surface for articulation with the head of the femoral component, and an outer metal portion fixed to the plastic portion against relative movement. The metal
30 portion includes a metal male conical taper surface. The male and female taper surfaces are mutually engagable taper-locking surfaces.

In accordance with another aspect of the present invention, a method of assembling an acetabular prosthesis for use with an implantable femoral prosthesis having a head is provided. The method includes providing a shell for fixation to bone, with the shell having an inner surface
5 defining a concavity and the inner surface including a metal female conical taper surface. An inner plastic insert portion is also provided having a plastic bearing surface for articulation with the head of the femoral prosthesis. An outer metal insert portion having a metal male conical taper surface is also provided. The male and female conical taper surfaces are
10 mutually engagable taper-locking surfaces. The inner plastic insert portion has an outer surface and the inner metal insert portion has an inner surface, and each of the inner and outer surfaces have mutually engagable means for fixing the outer metal insert portion to the inner plastic insert portion against relative movement. A temperature differential is induced
15 between said outer metal insert portion and said inner plastic insert portion to either expand the outer metal insert portion sufficiently or to contract the inner plastic insert portion sufficiently to permit the inner plastic insert portion to be received within the outer metal insert portion without interference between mutually engagable means for fixing. The inner
20 plastic portion is inserted within the outer metal insert portion, and the temperature differential is allowed to dissipate to permit the mutually engagable means for fixing to engage, thereby providing a composite bearing insert for receipt within the concavity of the shell. The composite bearing insert includes the outer metal insert portion fixed to the inner
25 plastic insert portion against relative movement. The composite bearing insert is inserted into the concavity of the shell such that the metal male conical taper surface engages the metal female conical taper surface in a taper locked relationship.

It is an object of the present invention to provide an acetabular
30 prosthesis having a shell for fixation to bone and having a bearing insert having a plastic bearing surface for articulation with the head of an

implantable femoral prosthesis, wherein the bearing insert can be inserted within the shell in the operating room and secured therein to avoid micro-motion between plastic and metal to alleviate formation of polyethylene debris during use of the acetabular prosthesis.

- 5 Other objects and advantages of the present invention will be apparent from the following descriptions of a preferred embodiment made with reference to the drawings.

Brief Description of the Drawings

FIG. 1 is a side view of an inner plastic portion of a bearing insert of
10 an acetabular prosthesis in accordance with the present invention, shown partially in section.

FIG. 2 is a cross-sectional view of an outer metal portion of a bearing insert of an acetabular prosthesis in accordance with the present invention.

15 FIG. 3 is a bottom end view of the outer metal portion of FIG. 2.

FIG. 4 is a cross-sectional view of a shell of an acetabular prosthesis in accordance with the present invention.

FIG. 5 is a bottom end view of the shell of FIG. 4.

FIG. 6 is an exploded cross-sectional view of the inner plastic
20 portion of FIG. 1 and the outer metal portion of FIG. 2 shown ready for assembly to each other.

FIG. 7 is a cross-sectional view of a composite bearing insert in accordance with the present invention comprised of the inner plastic portion of FIG. 1 and the outer metal portion of FIG. 2.

25 FIG. 8 is an exploded cross-sectional view of the composite bearing insert of FIG. 7 and the shell of FIG. 4 shown ready for assembly to each other.

FIG. 9 is an acetabular prosthesis in accordance with the present invention comprised of the composite bearing insert of FIG. 7 and the shell
30 of FIG. 4.

Best Mode for Carrying Out the Invention

Referring to FIG. 1, there is illustrated an inner plastic portion 10 of a bearing insert of an acetabular cup in accordance with the present invention. Plastic portion 10 is made of biocompatible ultra high molecular weight polyethylene, and includes an outer surface 12, an annular rim 14, and a bearing surface 16. Outer surface 12 is symmetrical about axis 18, and includes a cylindrical section 20 adjacent rim 14 followed by a partial spherical section 22 having an apex 24 intersecting axis 18. An annular protrusion 26 extends outwardly from outer surface 12 at the junction of cylindrical section 20 and partial spherical section 22. Annular protrusion 26 has a radiused surface that is convexly curved in planes parallel to axis 18. Annular rim 14 is flat and lies in a plane perpendicular to axis 18 and extends radially inwardly from cylindrical section 20 to bearing surface 16. Bearing surface 16 is hemispherical and extends axially inwardly from annular rim 14 to define a concavity 30 in which the spherical head of a femoral component can be received in articulating relationship.

Referring to FIGS. 2 and 3, there is illustrated an outer metal portion 32 of a bearing insert of an acetabular cup in accordance with the present invention. Metal portion 32 is designed to be fixed to inner plastic portion 10 of FIG. 1 to form a composite bearing insert, as described further below. Metal portion 32 is made of biocompatible metal, preferably titanium, and includes an outer surface 34 and an inner surface 36 joined by an annular rim 38. Outer surface 34 is symmetrical about axis 40, and includes a male conical taper surface 42 adjacent rim 38 followed by a partial spherical section 44 having an apex 46 intersecting axis 40. Male conical taper surface 42 tapers radially inwardly from rim 38 toward apex 46 at an angle of about 2° relative to axis 40. Male conical taper surface 42 therefore tapers at a total included angle of about 4°. Inner surface 36 is coaxial to outer surface 34 relative to axis 40 and is symmetrical about axis 40. Inner surface 36 includes a cylindrical section 48 adjacent rim 38 followed by a partial spherical section 50 having an apex 52 intersecting

axis 40. An annular groove 54 is located at the junction of cylindrical section 48 and partial spherical section 50. Annular groove 54 has a radiused surface that is concavely curved in a plane parallel to axis 40. A plurality of notches 56 are circumferentially spaced about inner surface 36 and are disposed in cylindrical section 48. Each notch 56 is elongated in a direction parallel to axis 40 and extends the axial length of cylindrical section 48 from rim 38 to annular groove 54. Notches 56 are radiused concavely in a plane perpendicular to axis 40, and are also radiused concavely at that end adjacent annular groove 54 in planes parallel to axis 40. Annular rim 38 is flat and lies in a plane perpendicular to axis 40 and extends radially inwardly from male conical taper surface 42 to inner surface 36. The junction of annular rim 38 and cylindrical section 48 of inner surface 36 is chamfered at chamfer 58.

Referring to FIGS. 4 and 5, there is illustrated a shell 60 of an acetabular cup in accordance with the present invention. Shell 60 is designed to be fixed to bone in the patient's acetabulum and to receive a composite bearing insert composed of inner plastic portion 10 of FIG. 1 and outer metal portion 32 of FIGS. 2 and 3, as described further below. Shell 60 is made of biocompatible metal, preferably titanium, and includes an outer surface 62 and an inner surface 64 joined by an annular rim 66. Outer surface 62 is symmetrical about axis 68, and is substantially hemispherical. Inner surface 64 is coaxial with outer surface 62 and symmetrical about axis 68 and includes a female conical taper surface 70 adjacent rim 66 followed by a partial spherical section 72 defining a concavity 74. Female conical taper surface 70 tapers radially inwardly away from rim 66 at an angle of about 2° relative to axis 68. Female conical taper surface 70 therefore tapers at a total included angle of about 4° . An apex hole 76 extends between outer surface 62 and inner surface 64 coaxially with axis 68 at the apex of shell 60. Apex hole 76 is internally threaded to facilitate engagement with a threaded instrument for handling and implanting shell 60 in the patient's acetabulum. A screw hole 78

extends between outer surface 62 and inner surface 64 at a location displaced from apex hole 76 by about 55° relative to axis 68. Screw hole 78 is conventionally configured to receive a bone screw inserted from within concavity 74 to extend outwardly into engagement with the bone of the patient's acetabulum to fix shell 60 to bone. Although only one screw hole 78 is illustrated, it should be understood that a plurality of screw holes are preferably provided at convenient locations on shell 60, as is well known in the art. Annular rim 66 is flat and lies in a plane perpendicular to axis 68 and extends radially inwardly from outer surface 62 to female conical taper surface 70.

Referring to FIG. 6, there is illustrated outer metal portion 32 and inner plastic portion 10 prior to their mutual assembly. The radii of curvature of respective partial spherical sections 50 and 22, the diameters of respective cylindrical sections 48 and 20, and the dimensions and locations of annular groove 54 and annular protrusion 26 are selected to provide a close fitting relationship between the outer surface 12 of inner plastic portion 10 and the inner surface 36 of outer metal portion 32. Nominally, outer surface 12 is dimensionally oversized relative to inner surface 36 such that when inner plastic portion 10 is disposed within outer metal portion 32 the polyethylene material of which inner plastic portion 10 is composed is under compression and in intimate contact with inner surface 36. Such compressive contact results in inner plastic portion 10 being frictionally fixed to outer metal portion 32, and also results in cold flow of the polyethylene of cylindrical section 20 into notches 56, thereby preventing rotation of inner plastic portion 10 relative to outer metal portion 32. The outer diameter of annular protrusion 26 of inner plastic portion 10 is sufficiently greater than the inner diameter of cylindrical section 48 of outer metal portion 32 at room temperature that inner plastic portion 10 cannot be inserted and seated within outer metal portion 32 due to mutual interference.

The preferred method of fixing outer metal portion 32 and inner plastic portion 10 together is to induce a temperature differential between the plastic and metal parts such that the plastic part contracts relative to the metal part sufficiently to permit the inner plastic portion 10 to be
5 received within the outer metal portion 32 without interference. This is preferably accomplished by cooling the inner plastic portion 10 in liquid nitrogen. The contracted plastic part is then inserted and seated and the temperatures of the respective parts are permitted to equilibrate such that nominal room temperature dimensions are restored and annular protrusion
10 26 is received and fixed within annular groove 54 to prevent relative axial displacement. The result is a composite bearing insert 80 as illustrated in FIG. 7, with the inner plastic portion 10 and the outer metal portion 32 effectively fixed to one another against relative movement.

Referring to FIG. 8, there is illustrated shell 60 and composite
15 bearing insert 80 in the form in which they would be provided to the implanting physician prior to implantation. The radii of curvature of respective partial spherical sections 72 and 44 are nominally identical, and the diameter of male taper surface 42 is nominally 4 ten-thousandths of an inch greater than the diameter of female taper surface 70.

20 In the preferred method of assembly, composite bearing insert 80 is inserted into the concavity 74 of shell 60 and seated with appropriate force to engage male conical taper surface 42 in taper locked relationship with female conical taper surface 70. The result, illustrated in FIG. 9, is that partial spherical section 44 is closely adjacent partial spherical section 72
25 and composite bearing insert 80 is fixed against axial and rotational movement relative to shell 60.

While the present invention has been illustrated and described with particularity in terms of a preferred embodiment and method of assembly, it should be understood that no limitation of the scope of the invention is
30 intended thereby. The scope of the invention is defined only by the claims appended hereto. It should also be understood that variations of the

particular embodiment described herein incorporating the principles of the present invention will occur to those of ordinary skill in the art and yet be within the scope of the appended claims. For example, the total included angle of the taper locking surfaces could be any of the angles known in the art to provide a self-locking engagement between metal conical tapers, with the understanding that as the angle increases the engaged tapers tend toward a self-releasing relationship and as the angle decreases diametrical tolerances become more critical to assure correct axial positioning of the components at the point of taper locking engagement. The outer metal portion of the composite bearing need not be constructed as a full hemispherical cup but could be an annular metal band carrying the male conical taper surface. Rather than relying on cold flow of the polyethylene into the notches of the outer metal portion of the bearing insert, the cylindrical section of the inner plastic portion could be provided with protrusions that are received within and engage the circumferentially spaced notches.

CLAIMS

1. An implantable acetabular prosthesis for articulating engagement with a head of an implantable femoral prosthesis, comprising:
a shell for fixation to bone, said shell having an inner surface defining a concavity, said inner surface including a metal female conical
5 taper surface; and
a composite bearing insert for receipt within said concavity of said shell, said composite bearing insert including an inner plastic portion having a plastic bearing surface for articulation with the head of said femoral component, and an outer metal portion fixed to said plastic portion
10 against relative movement, said metal portion including a metal male conical taper surface;
said male and female taper surfaces being mutually engagable taper-locking surfaces.
2. The acetabular prosthesis of Claim 1, in which said inner plastic insert portion and said outer metal insert portion include mutually engaged means for fixing said outer metal insert portion to said inner plastic insert portion against relative movement.
3. The acetabular prosthesis of Claim 2, in which said means for fixing fixes said inner plastic insert portion against axial movement relative to said outer metal insert portion.
4. The acetabular prosthesis of Claim 3, in which said means for fixing fixes said inner plastic insert portion against rotational movement relative to said outer metal insert portion.
5. The acetabular prosthesis of Claim 3, in which said means for fixing includes an annular groove in said outer metal insert portion and an annular protrusion on said inner plastic insert portion received in said annular groove.
6. A method of assembling an implantable acetabular prosthesis for use with an implantable femoral prosthesis having a head, comprising the steps of:

(a) providing a shell for fixation to bone, said shell having an inner
5 surface defining a concavity, said inner surface including a metal female
conical taper surface;

(b) providing an inner plastic insert portion having a plastic bearing
surface for articulation with the head of said femoral prosthesis;

(c) providing an outer metal insert portion having a metal male
10 conical taper surface;

said male and female conical taper surfaces being mutually
engagable taper-locking surfaces;

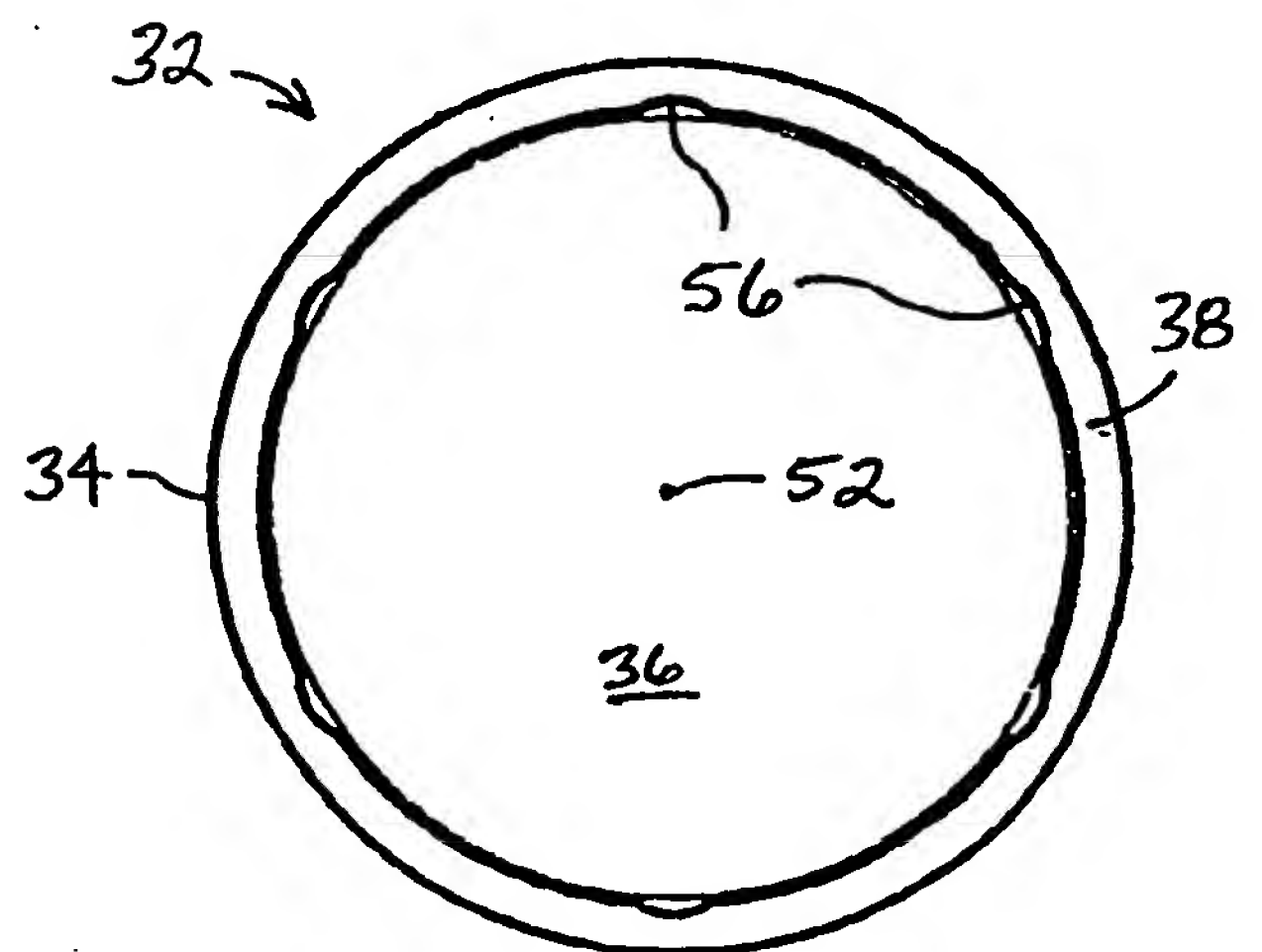
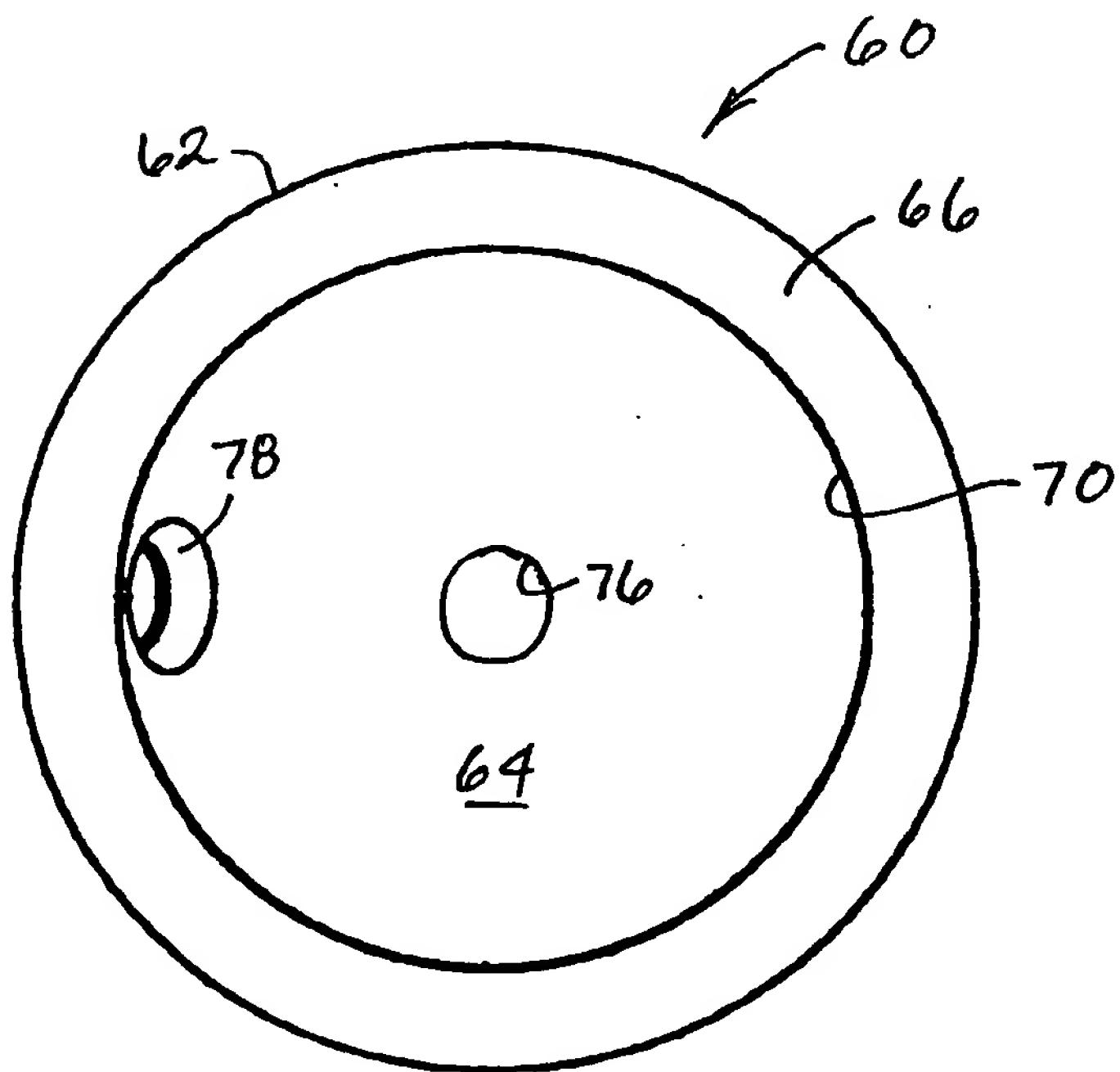
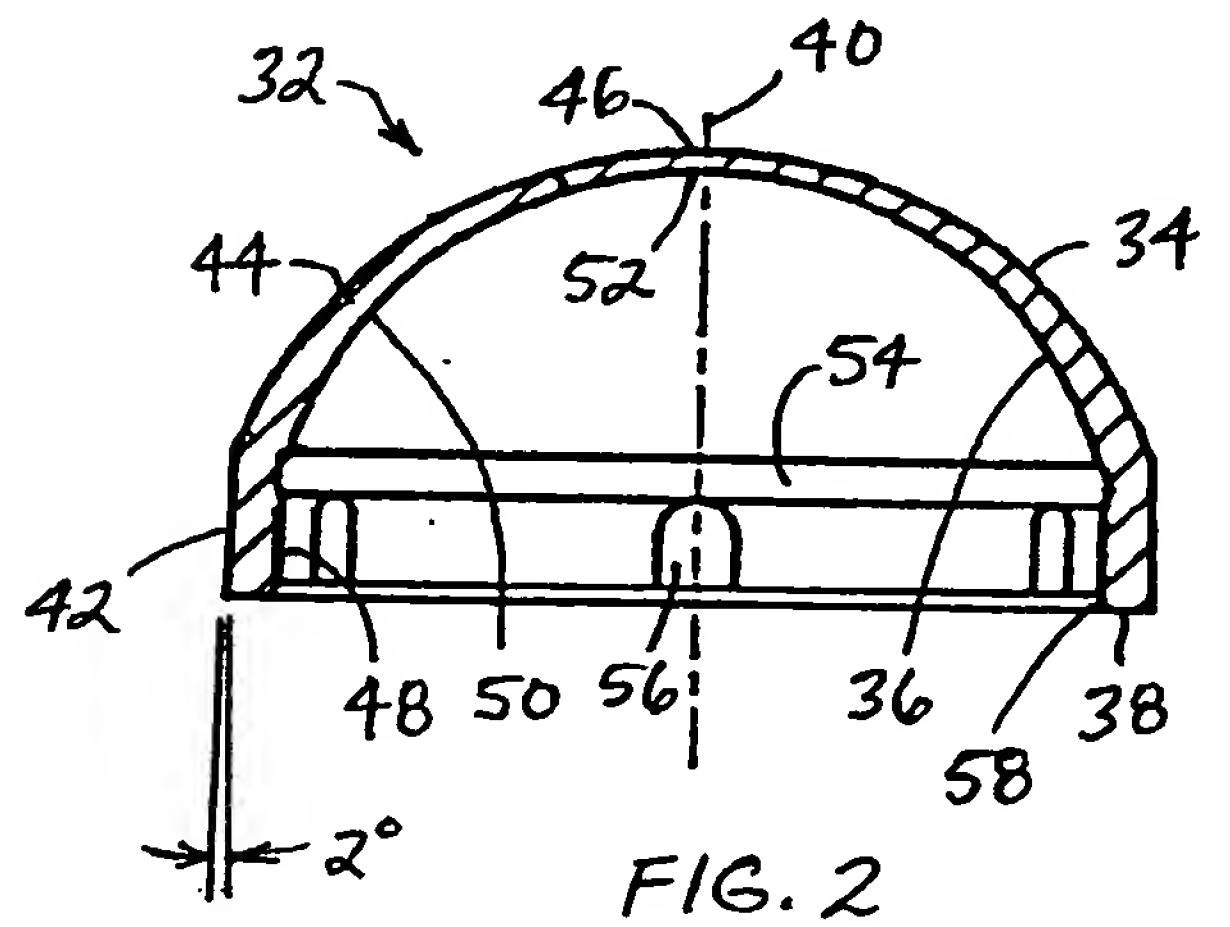
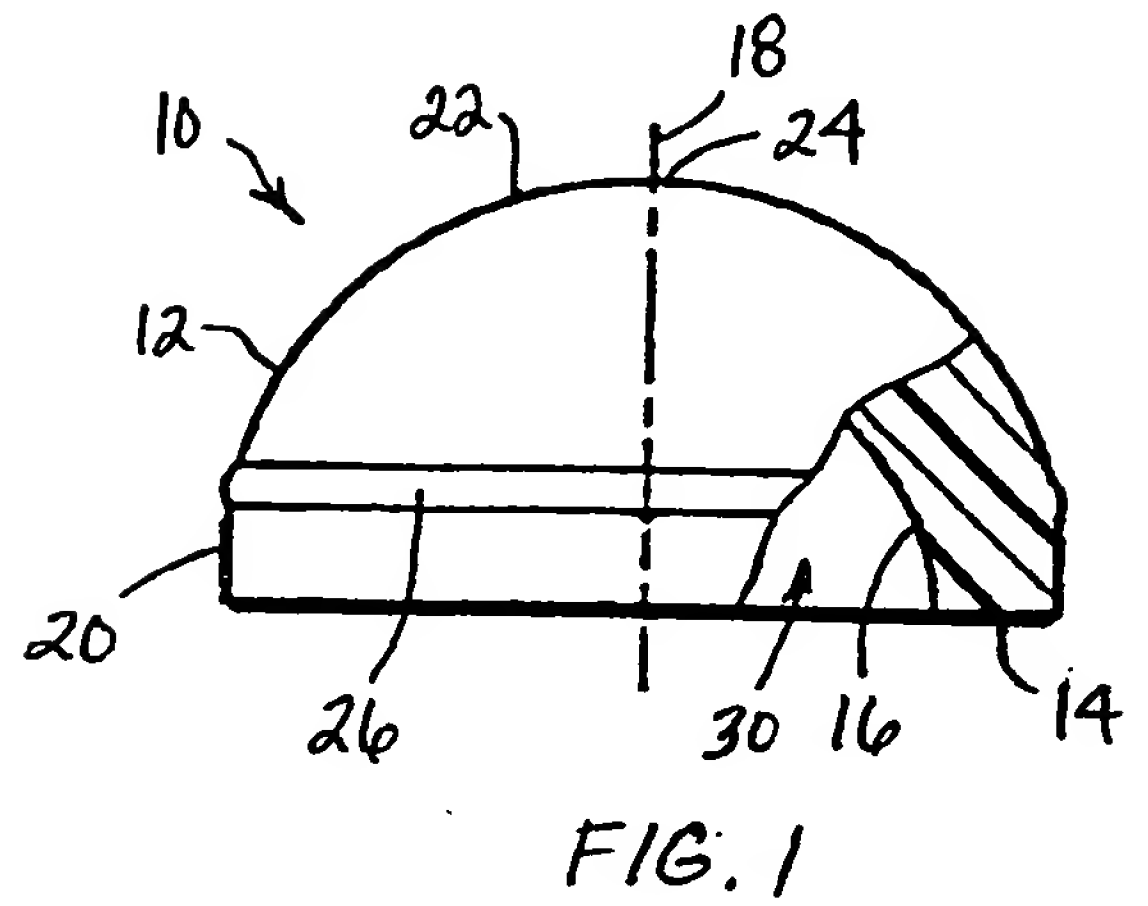
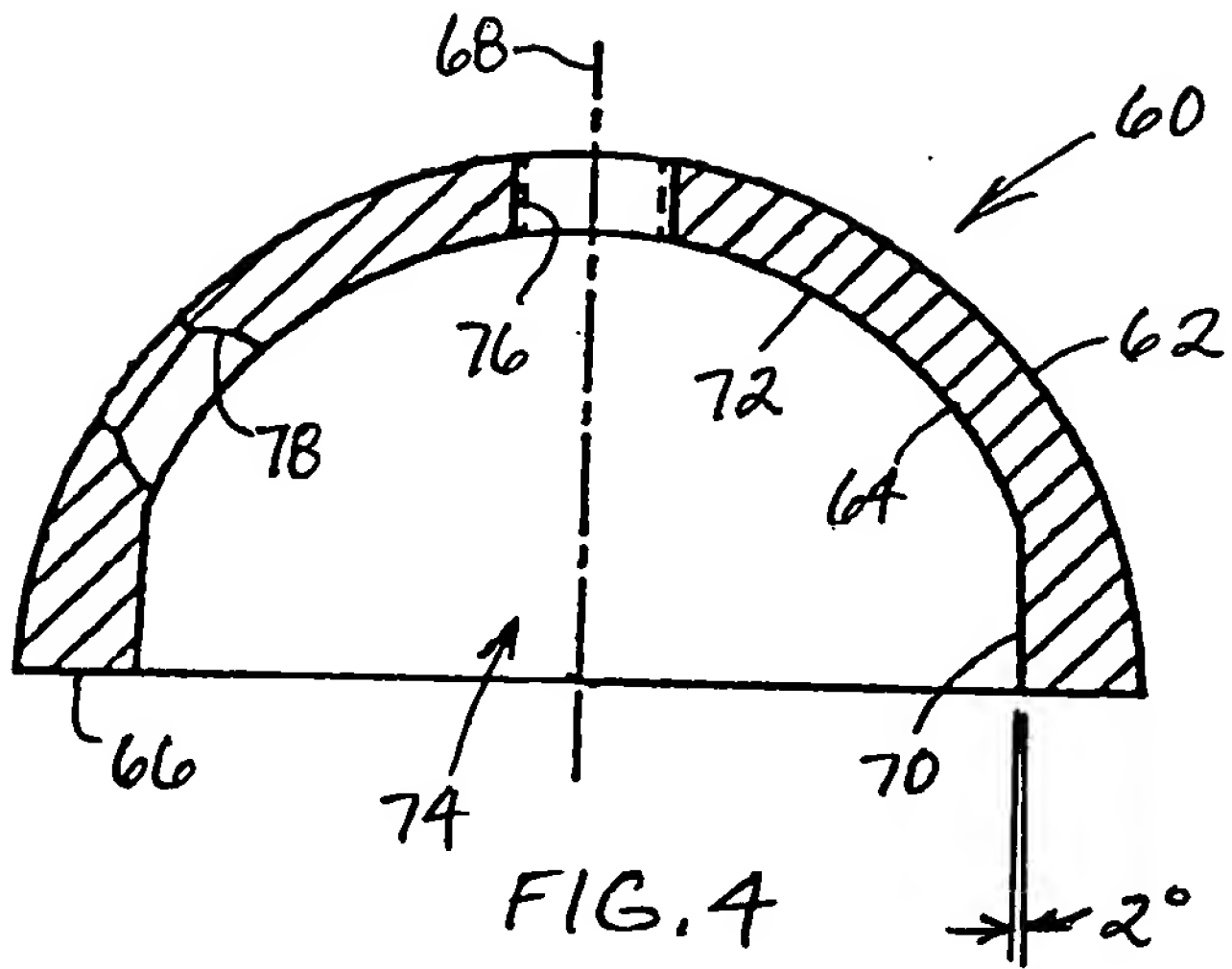
said inner plastic insert portion having an outer surface and said
inner metal insert portion having an inner surface, each of said inner and
15 outer surfaces having mutually engagable means for fixing said outer metal
insert portion to said inner plastic insert portion against relative movement;

(d) inducing a temperature differential between said outer metal
insert portion and said inner plastic insert portion to either expand said
outer metal insert portion sufficiently or to contract said inner plastic insert
20 portion sufficiently to permit said inner plastic insert portion to be received
within said outer metal insert portion without interference between said
mutually engagable means for fixing;

(e) inserting said inner plastic portion within said outer metal insert
portion;

25 (f) allowing said temperature differential to dissipate to permit said
mutually engagable means for fixing to engage, thereby providing a
composite bearing insert for receipt within said concavity of said shell, said
composite bearing insert including said outer metal insert portion fixed to
said inner plastic insert portion against relative movement; and

30 (g) inserting said composite bearing insert into said concavity of said
shell such that said metal male conical taper surface engages said metal
female conical taper surface in a taper locked relationship.



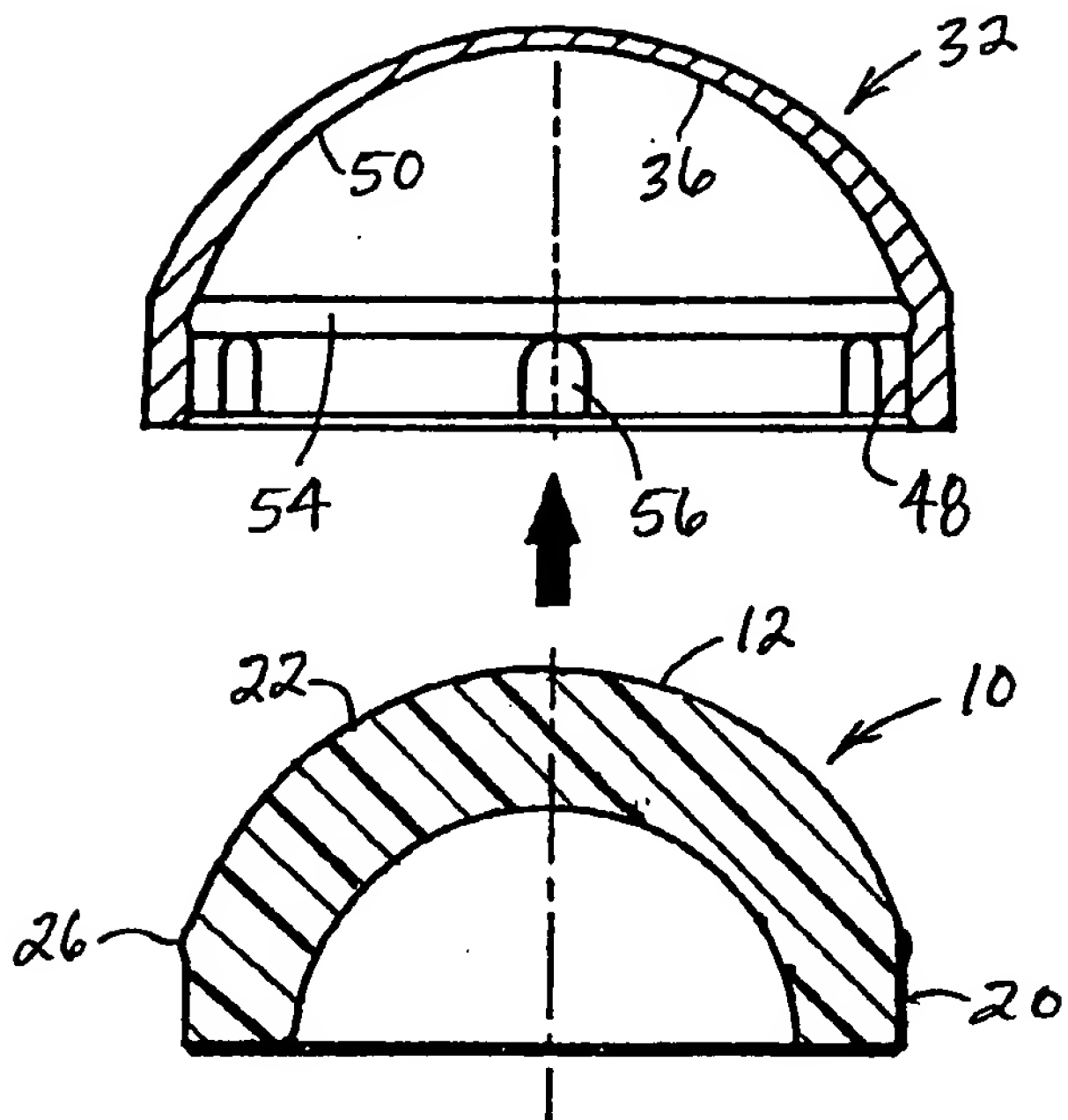


FIG. 6

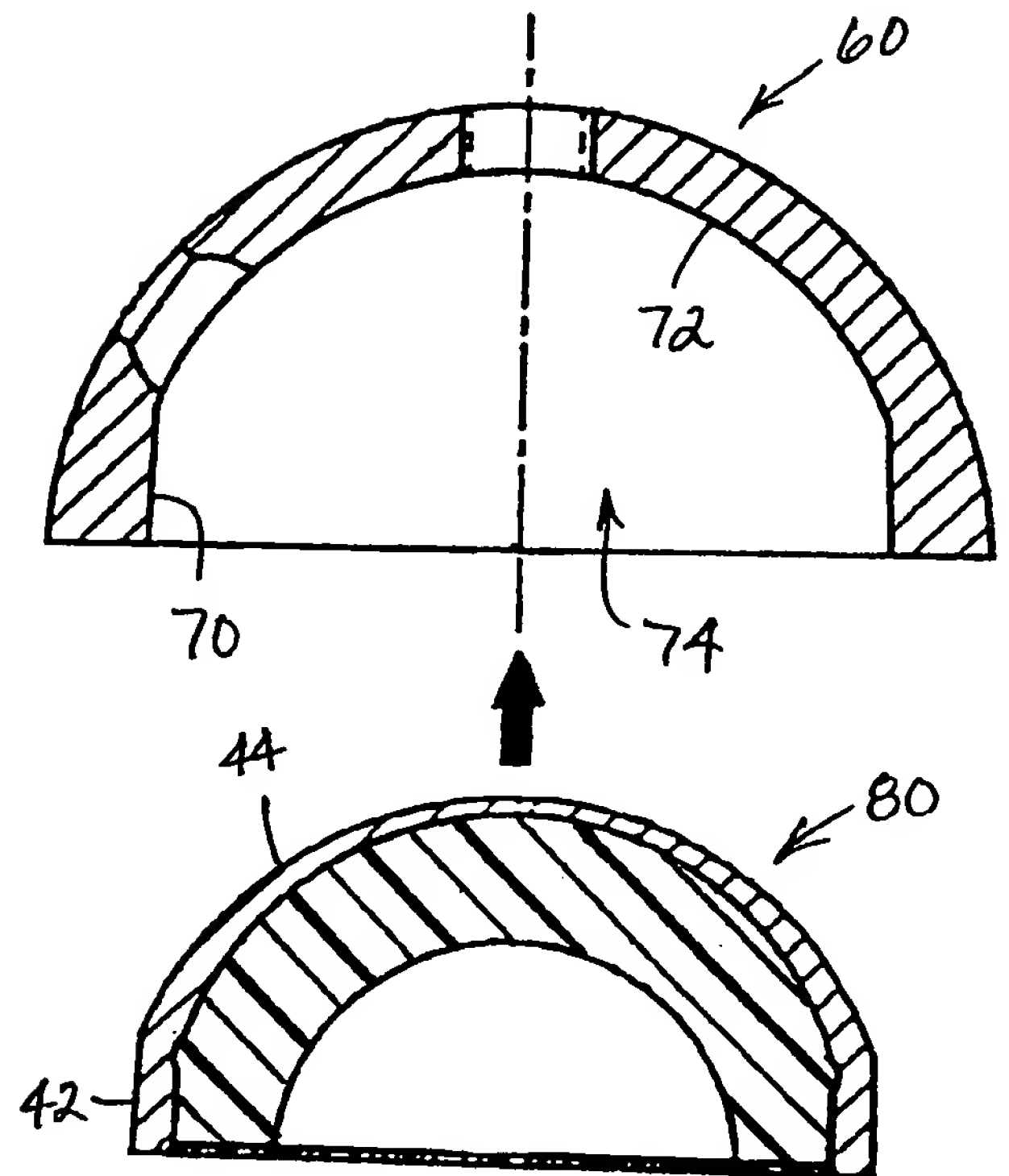


FIG. 8

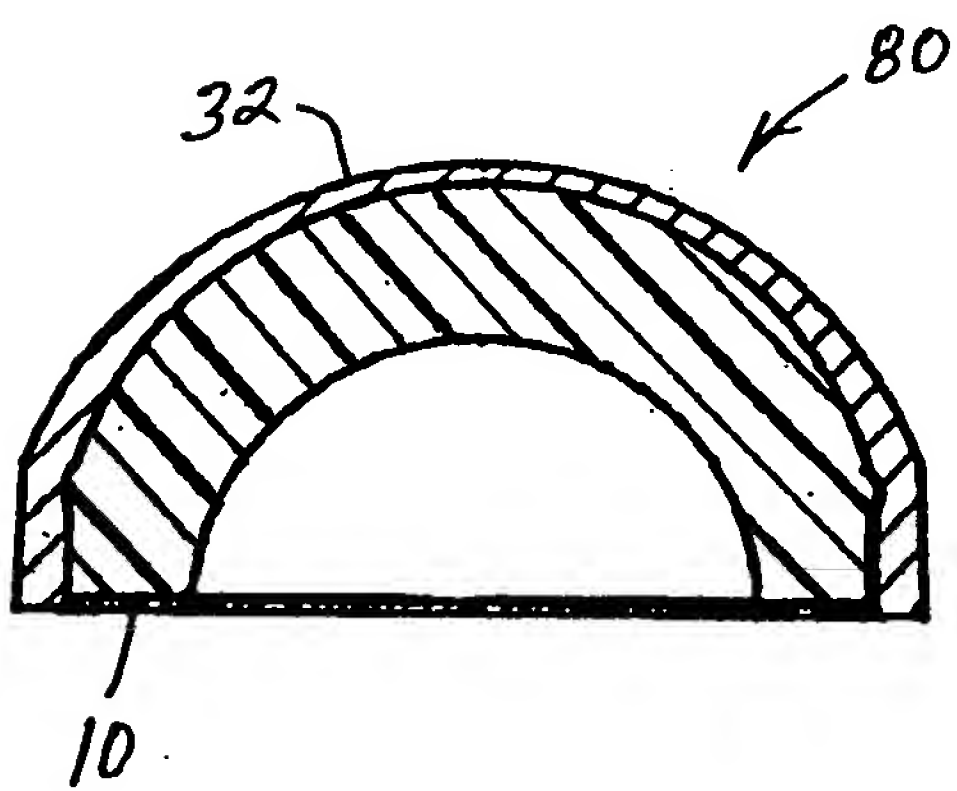


FIG. 7

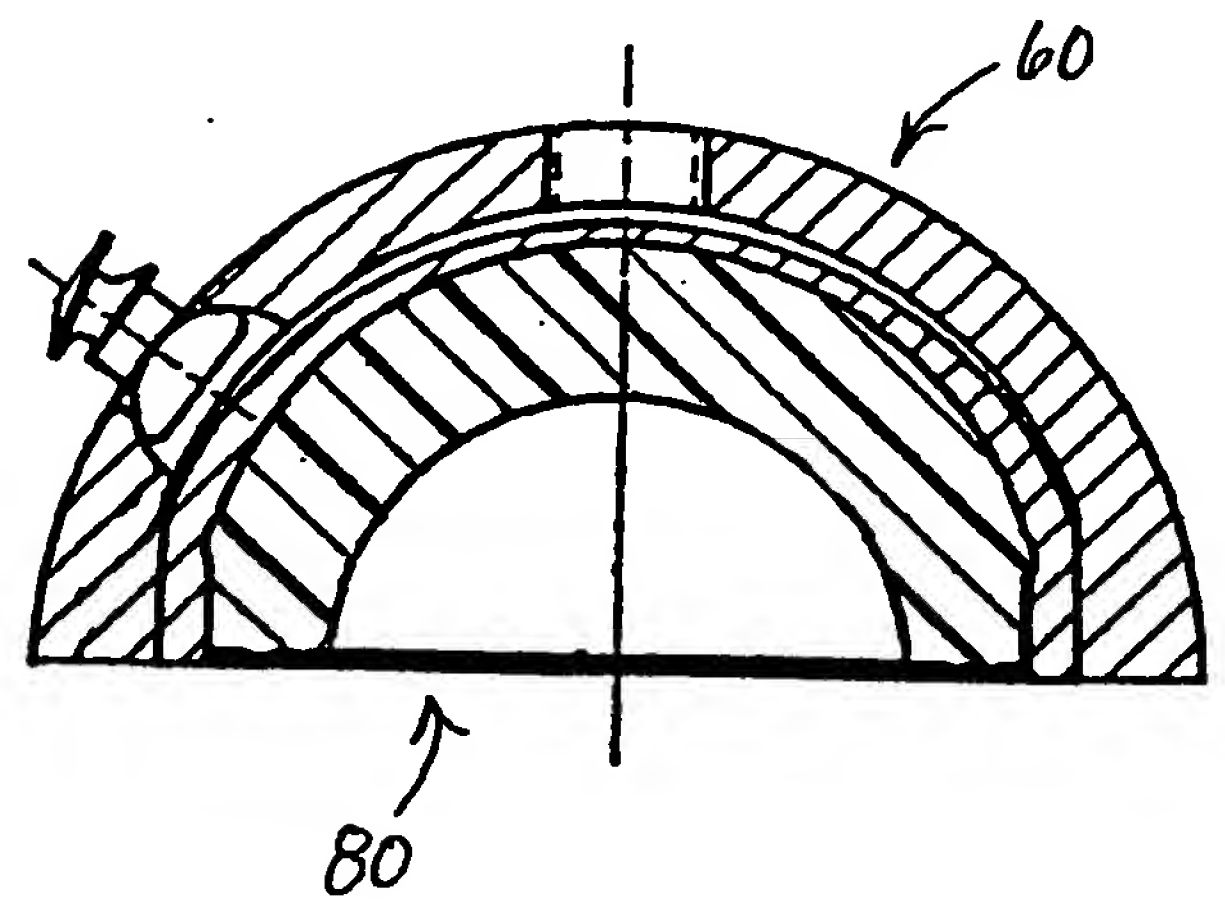


FIG. 9

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US95/02334

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61F 2/34

US CL :623/022

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/011, 016, 018, 022, 023. 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
NONEElectronic data base consulted during the international search (name of data base and, where practicable, search terms used)
NONE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US, A, 4,963,154 (ANAPLIOTIS ET AL.) 16 October 1990. See detailed description.	1-3, 5, 6
Y	US, A, 4,681,589 (TRONZO) 21 July 1987. See the detailed description.	1-3, 5, 6,
Y	US, A, 4,878,916 (RHENTER ET AL.) 07 November 1989. See detailed description.	6

☐ Further documents are listed in the continuation of Box C.☐ See patent family annex.

* Special categories of cited documents:	*T	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be part of particular relevance	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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Date of the actual completion of the international search

28 MARCH 1995

Date of mailing of the international search report

14 APR 1995

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